IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division

OUTSOURCING FACILITIES ASSOCIATION, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	Civil Action No. 4:25-cv-174-P

Plaintiffs' Memorandum of Law in Opposition to Defendants' and Defendant-Intervenor's Motions for Summary Judgment

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Introduction

The Court should deny the summary judgment motions filed by the Food and Drug Administration (FDA) and Novo Nordisk (Novo Nordisk) (collectively, Defendants). The motions fail to address the critical deficiencies identified by Plaintiffs in the FDA's decision resolving the semaglutide shortage (the "Delisting Action" or the "Decision"), and they do not justify judgment as a matter of law in favor of Defendants.

Argument

I. Defendants Are Not Entitled to Summary Judgment on the Second, Third, and Fourth Claims

Defendants should not be awarded summary judgment on the second cause of action, which challenges the FDA's failure to provide a satisfactory explanation of the grounds of the Delisting Action, Compl. ¶¶ 61–65; the third cause of action, which challenges the FDA's findings as arbitrary and capricious under the substantial evidence standard, *id.* ¶¶ 66–69; and the fourth cause of action, which challenges the FDA's dismissal of evidence of an ongoing shortage as arbitrary and capricious under the substantial evidence standard, *id.* ¶¶ 70–75. As Plaintiffs' motion for summary judgment explains, ECF No. 71 ("Plaintiffs Mem.") at 7–21, the FDA's decision failed to address "obvious" questions, *10 Ring Precision, Inc. v. Jones*, 722 F.3d 711, 724 (5th Cir. 2013), and [redacted] *Chamber of Com. of United States of America v. Dep't of Lab.*, 885 F.3d 360, 382 (5th Cir. 2018). Defendants' summary judgment motions simply repeat the assertions of the Decision. ECF No. 73 ("NNI Mem.") at 9–18; ECF No. 69 ("FDA Mem.") at 7–14. Because the Decision erred by omission, Defendants' summary judgment motions are equally infirm.

A. The Decision Failed To Account for Compounding Supply

[redacted]

[redacted] Defendants have nothing to say of this, even though Plaintiffs presented this same argument in their preliminary-injunction reply brief. ECF No. 60 at 2–3 ("Plaintiffs.PI.Reply").

It is, in any event, too late for the FDA to address this hole, given that *post hoc* justifications cannot save the Delisting Action's material omissions. *See Louisiana v. Dep't of Energy*, 90 F.4th 461, 477 (5th Cir. 2024). Nor may Defendants persuasively argue that the FDA was free to ignore these facts. As noted, an agency's decision must address "obvious" topics, *10 Ring Precision*, 722 F.3d at 724, and compounding volume is such a topic. [redacted]

[redacted]

Accordingly, the FDA's Decision "fails to account for 'relevant factors' [and] evinces 'a clear error of judgment.'" *Univ. of Texas M.D. Anderson Cancer Ctr. v. United States Dep't of Health & Hum. Servs.*, 985 F.3d 472, 475 (5th Cir. 2021) (citation omitted). The "result reached is 'illogical on its own terms,'" and is therefore "arbitrary and capricious." *Am. Fed'n of Gov't Emps., Loc. 2924 v. Fed. Lab. Rels. Auth.*, 470 F.3d 375, 380 (D.C. Cir. 2006); *Harrell v. Harris*, 610 F.2d 355, 359 (5th Cir. 1980); *City of Charlottesville v. FERC*, 661 F.2d 945, 952 (D.C. Cir. 1981).

B. The Decision Failed To Address Direct Evidence of a Shortage

[redacted]

This evidence, too, featured prominently in Plaintiffs'

preliminary-injunction reply brief, Plaintiffs.PI.Reply 8–9, but Defendants have nothing to say about it. The point also was neglected in the Decision. This fact alone defeats Defendants' motions for summary judgment.

C. Defendants' Interpretations of Novo Nordisk's Supply and Demand Data Are Inconsistent With the Record

Defendants' summary judgment briefing underscores the deficiencies in Novo Nordisk's supply and demand data. Novo Nordisk and the agency defend Novo Nordisk's figures, but [redacted]

1. [redacted] But supply is only relevant as compared to demand. [redacted] *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983) ("[T]he courts may not accept

appellate counsel's *post hoc* rationalizations for agency action. It is well-established that an agency's action must be upheld, if at all, on the basis articulated by the agency itself.").

2. [redacted]. *See U.S. Air Tour Ass'n v. FAA*, 298 F.3d 997, 1015–18 (D.C. Cir. 2002) (vacating FAA flight restrictions because the agency failed to explain why it measured "natural quiet" by the "average annual day" rather than "any given day"). [redacted] Yet it has nothing to say of this now. [redacted] Novo Nordisk's brief is silent on it. [redacted] *Cf. State Farm*, 463 U.S. at 49 (observing that agency should not defer to industry choices in decision-making). [redacted]

[redacted]

That assertion is inadequate.

3. [redacted]

[redacted]

4. [redacted]

[redacted] That is a meaningless assertion. [redacted]

The FDA's briefing is similarly deficient. [redacted]

[redacted]

5. [redacted]

[redacted] But it leaves out two key points. [redacted]

[redacted]

[redacted] But that is not right. [redacted]

[redacted]

6. [redacted]

[redacted]

[redacted]

7. [redacted], *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) ("[T]he requirement that an agency provide reasoned explanation for its action would ordinarily demand that it display awareness that it is changing position."); *Nat'l Ass'n of Manufacturers v. SEC*, 105 F.4th 802, 811 (5th Cir. 2024) (finding agency departure from past findings without explanation arbitrary and capricious). [redacted]

D. Defendants Fail To Justify the Agency's Dismissing Shortage Evidence

In addition to the evidence never considered, *see* § I.B, *supra*, Defendants fail to justify the agency's handwaving dismissal of the non-Novo Nordisk evidence it did consider. *See Sutter E. Bay Hosps. v. N.L.R.B.*, 687 F.3d 424, 437 (D.C. Cir. 2012). [redacted]

[redacted] Defendants miss the forest for the trees. [redacted] The agency, and Defendants' briefing, never grapples with this interplay, instead parsing each piece of evidence for any arguable shortcoming. *Cf. United States v. Maynard*, 615 F.3d 544, 562 (D.C. Cir. 2010) (recognizing that multiple "types of information" taken together can "reveal more" than the individual components "viewed in isolation"). [redacted]

II. Defendants Are Not Entitled to Summary Judgment on the Fifth Claim

Defendants should not be awarded summary judgment on the fifth cause of action, which challenges the FDA's reading of governing statutes. Compl. ¶¶ 76–82.

[redacted]

[redacted]

In fact, it is Defendants' argument that leads to absurd results. [redacted]

Second, [redacted] As Plaintiffs explained, 21 U.S.C. § 356c's definition of shortage is inconsistent with requiring a "national" failure of supply to meet demand. Plaintiffs Mem. 21–22. Under the plain meaning of the statute, a shortage in New England or in the Midwest are shortages "in" and "within" the United States, but they would be dismissed under the Defendants' interpretation of the statute if they were not representative of a national shortage. Congress could have defined shortage as a period of time where demand exceeds supply at a national level. It did not, instead choosing words that allow for regional shortages to be recognized and cured by compounders – consistent with Congress's intent that patients have access to critical drugs even when the manufacturer cannot supply them, whether that be across the nation or in one region of the nation.

Finally, Novo Nordisk never mentions, and the FDA does not meaningfully engage with, the reality that the agency must consider shipping delays as part of its shortage analysis. 21 U.S.C. § 356e(b)(F). [redacted]

[redacted] FDA Mem. 8, but it is evidence of the opposite. [redacted] This conclusion stems from an incorrect interpretation of the definition of shortage and is therefore erroneous.

III. Defendants Are Not Entitled to Summary Judgment on the First and Sixth Claims

Defendants should not be awarded summary judgment on the first cause of action, which challenges the FDA's promulgation of the Delisting Action without notice-and-comment rulemaking, Compl. ¶¶ 51–60; and on the sixth cause of action, which challenges the FDA's failure to publish the Delisting Action in the Federal Register, *id.* ¶¶ 83–87.

1. As an initial matter, Plaintiffs' notice-and-comment argument is not a "Catch 22," NNI Mem. 20, for three reasons. First, the argument ignores the Court's jurisdictional and statutory limitations: the Court has no vehicle to consider, or invalidate, the original listing decision because there is no plaintiff before the Court with standing to challenge the decision. Second, the APA directs that the process "required" to promulgate a rule be used to rescind it, not that whatever the agency did at the outset necessarily applies to amendments or repeal. *See Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 101 (2015). Finally, the FDA's Decision can only stand on the basis the FDA supplied in the action itself. *See Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 20 (2020). The agency did not state that a basis for the Decision is invalidity of the original listing action. And if the agency had made such a statement, it would have been required to consider obvious alternatives to rescinding the rule, such as justifying the Decision under notice and comment's "good cause" exception. 5 U.S.C. § 553(d)(3). There is no Catch-22.

2. Defendants' substantive arguments are also off base. The APA requires agencies to follow notice-and-comment procedures for "substantive" or "legislative" rules—that is, "those which create law." *Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 628 (5th Cir. 2001). Novo Nordisk calls the agency's action a "paradigmatic adjudication," NNI Mem. 19, yet does not identify any other case where an administrative agency conducted an adjudication without any parties. Far from paradigmatic, the agency's action here "had all of the qualities of a legislative rule" requiring notice

and comment because it applied prospectively to an entire industry. *Safari Club Int'l v. Zinke*, 878 F.3d 316, 323–24 (D.C. Cir. 2017); *see also Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 221 (1988) (Scalia, J., concurring) ("Adjudication deals with what the law was; rulemaking deals with what the law will be."). The FDA contends its Decision "had none of the characteristics of a rule," FDA Mem. 17, yet its Order acknowledges that what was once legal (compounding) is no longer legal going forward, Order 9. Rules have "only 'future effect' while adjudications immediately bind parties by retroactively applying law to their past actions." *Safari Club*, 878 F.3d at 333. Because the Decision is a legislative rule, the agency was required to engage in notice and comment.

3. The FDA's argument that "adjudication was the only viable option" for maintaining the shortage list ignores the text and is practically incorrect. FDA Mem. 15. The APA requires any law superseding the default rule to do so "expressly." 5 U.S.C. § 559; *see also Mann Constr. Inc. v. United States*, 27 F.4th 1138, 1146 (6th Cir. 2022). Yet the FDA does not even argue that the APA has been expressly superseded in this case. To the extent the agency implies the "up-to-date" requirement or the confidentiality of the material it receives absolves it from following notice and comment, it is mistaken. The FDA can update the shortage list frequently through notice-and-comment rulemaking—or by finding good cause when necessary to act without rulemaking—such that the statutory scheme remains "compatible with the APA." *Id.* at 1145 (citation omitted). Neither the Decision nor the briefing explain how, why, or if the agency considered its ability to proceed in this manner.

Further, agencies conduct rulemaking all the time using confidential information, including about things such as nuclear facilities. *See Pub. Citizen v. Nuclear Regul. Comm'n,* 573 F.3d 916 (9th Cir. 2009). The FDA itself has well-established norms and procedures for handling classified information while respecting the APA's requirements. *See* FDA, "Procedures for Handling Confidential Information in Rulemaking." 60 Fed. Reg. 66981 (Dec. 27, 1995); *see also* FDA, Consumer Comments—Public Posting and Availability of Comments Submitted to Food and Drug Administration Dockets, 80 Fed. Reg. 56469 (Sept. 18, 2015) (updating 1995 policy). The

agency's justifications for avoiding notice-and-comment procedures are not exceptions found anywhere in the statutes—as such, there is no "express[]" overruling of the APA's requirements.

4. The agency's harmless error argument, FDA Mem. 18–19, which Novo Nordisk does not join, misses the mark. First, the Fifth Circuit has held that no showing of prejudice is necessary when agencies fail to subject substantive rules to notice and comment. *See W & T Offshore, Inc. v. Bernhardt*, 946 F.3d 227, 237 (5th Cir. 2019). Second, even if prejudice was necessary, the prejudice here is evident. The FDA argues potential commenters should have been aware of an obscure page on the agency's website, FDA Mem. 19–20, but that is incorrect. A post buried on a website is not the same as *Federal Register* notice. Further, the web posting did not include important information, such as what information was the agency looking for, during what time periods, and how would the agency evaluate it? Only Novo Nordisk had a direct line with the agency, and was therefore able to tailor its presentations in the best way possible. Defendants are not entitled to summary judgment on the first claim.

5. Finally, the complications caused by the agency's failure to notify the public is why the APA obligates agencies to "publish in the Federal Register … (D) substantive rules of general applicability adopted as authorized by law." 5 U.S.C. § 552(a)(1)(D). This "was adopted to provide, inter alia, that administrative policies affecting individual rights and obligations be promulgated pursuant to certain stated procedures so as to avoid the inherently arbitrary nature of unpublished ad hoc determinations." *Morton v. Ruiz*, 415 U.S. 199, 232 (1974). The Delisting Action is a legislative rule that was not published in the Federal Register, and therefore Defendants are not entitled to summary judgment on the sixth claim.

Conclusion

The Court should deny Defendants' summary judgment motion. The Court should enter summary judgment in favor of Plaintiffs, set aside the Delisting Action, and permanently enjoin the FDA from taking action based on the Delisting Action.

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